K052920

3 PREDICATE DEVICES

OmniPro I'mRT	
510(k) number	K031634
Trade name	OmniPro I'mRT
Intended Use	The intended use of the OmniPro I'mRT system is to: • Verify the treatment plan and delivered dose of intensity modulated or static beams prior to treatment • Verify the intensity maps during IMRT delivery prior to treatment • Verify the absolute dose in given points for IMRT fields.
Company	Scanditronix Wellhöfer GmbH Bahnhofstraße 5 D-90592 Schwarzenbruck Germany http://www.scanditronix-wellhofer.com/

MapCheck	
510(k) number	unknown
Trade Name	MapCheck
Intended Use	"The MapCHECK™ is a 2-dimensional therapy beam measurement system intended for quick and precise verification of the dose distribution resulting from an IMRT plan. Beam measurement is accomplished using a grid of 445 diode detectors that are housed between two sheets of solid acrylic. The MapCHECK measures the integrated ABSOLUTE dose at all detector locations, each of which has been corrected to the central detector sensitivity. This measured dose map is then automatically normalized and compared to a normalized imported treatment plan dose map, all in less than one minute." (citet from the company's homepage: http://www.sunnuclear.com, MapCHECK Model 1175)
Company	Sun Nuclear Corporation 425-A Pineda Court Melbourne, FL 32940 USA www.sunnuclear.com

Dynamic Thorax Phantom	
510(k) number	unknown
Trade Name	CIRS Model 008 Dynamic Thorax Phantom
Intended Use	"The CIRS Model 008 Dynamic Thorax Phantom is designed to investigate and minimize the impact of organ motion and patient positioning errors in radiation therapy. It is the first commercially available dynamic QA phantom, developed for image acquisition, treatment planning and dose delivery."

	Dynamic Thorax Phantom
	(citet from the company's homepage http://www.cirsinc.com/ , IMRT/IGRT 4D QA Phantom)
Company	CIRS, Inc. 2428 Almeda Avenue, Suite 212 Norfolk, VA 23513 USA http://www.cirsinc.com

4 DESCRIPTION OF THE NEW DEVICE

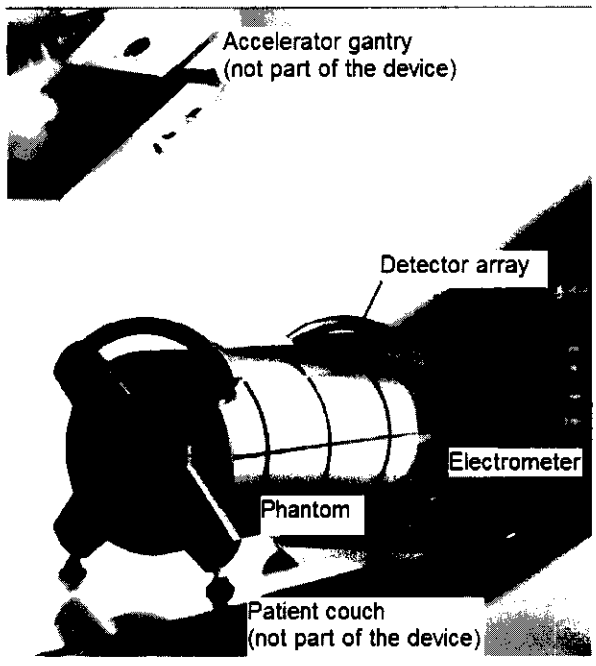
The intended use of the new device is quality assurance of patient specific treatment delivery prior to the treatment in IMRT and 4DRT (respiratory gating and tumour tracking).

The new device consists out of:

- software
- phantom
- Detector arrays.
- Multi-channel electrometer
- Connection cables

When measurements are to be performed the device is typically put on the patient table (or couch). Then the device is exposed typically from different angles.

Below the device is shown schematically in a typical environment. Note that the detector arrays are barely visible, since they are mounted inside the phantom. The software and connection cables are not shown.



4.1 General Challenge

The physicist wants to verify the dose-distribution in a patient.

However, in most cases it is not possible to measure the dose directly in the patient.

The principal solution is to substitute the patient with a phantom similar to the human body regarding size and physical properties like density or electron-density. Inside this phantom detectors are mounted. These detectors can measure the dose distribution when exposing the phantom to a patient specific treatment scheme.

4.2 Typical workflow in IMRT

1. The phantom is scanned in a CT (computer tomograph). This needs to be done only once. The CT is not part of the new device.
2. A plan for a specific patient is applied onto the phantom. This is done in a TPS (Treatment Planning System). The TPS is not part of the new device.
3. The dose distribution in the phantom is calculated by the TPS.
4. The calculated dose distribution is exported from the TPS to the new device's software.
5. The phantom - with the detector matrix mounted inside the phantom - is exposed with the patient-specific plan. The dose is measured and ready for analysis in the device's software.
6. The calculated and the measured dose are compared inside the device's software.
7. A report is printed.

4.3 Typical workflow in 4DRT

The workflow is the same as for IMRT with the following exceptions:

- Not only one dose plan is calculated and applied. Two or more dose plans may be calculated per patient. For example for respiratory gating two plans may be calculated representing two phases in the respiratory cycle; during one phase the beam shall be ON, during the other OFF..
- When exposing the phantom with the patient specific plan(s) trigger signals may be used to flag the phase (e.g. beam on or beam off in the above example). The dose distribution is saved individually for the different phases and can be compared with the calculated dose distribution planned for the respective phase.

4.4 Scientific concept

The detectors in the detector array are semiconductors, no external voltage (as necessary for ion-chambers) is applied.

When irradiating semiconductors a current is created; this current is measured in the electrometer.

4.5 Material used

The phantom material is a plastic material that is

- similar to human tissue regarding density and electron density
- non toxic (approved for food contact)

5 INTENDED USE

The **intended use** of the product is quality assurance of patient specific treatment delivery prior to the treatment in IMRT and 4DRT (respiratory gating and tumor tracking).

Environment: Radiotherapy Department

Typical user: Physicist or other dosimetry expert

Contact with patient: No.

Note: Only one of the predicate devices, the dynamic thorax phantom, is explicitly intended for quality assurance in 4D RT.

It is an advantage that the new device not only can be used for quality assurance in IMRT but also in 4DRT.

- The customer can automatically perform quality assurance in one single session. This avoids two exposures only because the IMRT measurement instruments must be substituted with a 4DRT measurement instrument.

6 TECHNOLOGICAL CHARACTERISTICS.

6.1 Detector(s)

The new device like one of the predicate devices use semiconductors as detectors, two predicate devices use other technologies like ionization chambers, TLDs or film (among others).

The advantages of semiconductors compared to ionization chambers are:

- Small volume (The smaller the detector volume the better is the spatial resolution.)
- No external high voltage

The advantages of semiconductors compared to films or TLD are:

- Readout with high time resolution possible
- Readout online

6.2 Phantom Material

The density and the electron density are all in the range of human tissue (between fat and bone).

6.3 Energy source

The energy source is the same for all devices (normal power outlet)

None of the devices delivers energy to the patient or the user.

7 NON-CLINICAL TESTS

The technology used is the same as used as in one of the predicate devices. This technology (semiconductors) is widely used in the field of dosimetry in radiation therapy, especially when measurements are to be performed on or in a patient (in vivo dosimetry). The most important reason for the latter is that this technology is seen as inherently safe due to the absence of high voltage. This technology is well known and explicit tests in laboratories are not necessary to show equivalence.

The following is done to minimize potential electrical risks:

- The new device is designed for conformance with IEC 601-1 (electrical isolation, leakage current) and IEC 601-1-2 (electromagnetic compatibility)
- Each unit is subject to final performance testing.

8 CLINICAL TESTS

Clinical tests are not necessary; however, the device has been tested in a clinical environment.

9 CONCLUSION

The new device is partly better, partly equivalent and in some cases identical with the predicate devices regarding safety, design and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2006

Mr. Thomas Matzen
Diplom Physiker
ScandiDos AB
Dag Hammarskjölds väg 52A[4]
Uppsala Science Park
Uppsala, SE-752 37
SWEDEN

Re: K052920
Trade/Device Name: Delta[4]
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 16, 2005
Received: December 19, 2005

Dear Mr. Matzen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Document Title: **510(k): Indication for Use** Subject: **Pre-treatment System**		Document ID: K052920 D001 04 002 01	Page 7_1
Author: Thomas Matzen	Signature	Date 2005-04-07	

Applicant	ScandiDos AB
510(k) Number (if known):	
Device Name:	Delta^4
Indications for Use:	The intended use of Delta^4 is quality assurance of patient specific treatment delivery prior to the treatment in IMRT and 4DRT (respiratory gating and tumor tracking).

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052920